UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,138	03/07/2007	David Bergman	514862002700	1090

20872 7590 04/23/2009

MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
04/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,138	BERGMAN ET AL.	
	Examiner	Art Unit	
	JACQUELINE DIRAMIO	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *13-16,21,24,26-52 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 – 12, 17 – 20, 22, 23, 25 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/05; 3/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 – 25 and 53, in the reply filed on March 2, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In addition, Applicant's species election of Group A1 (claim 12), Group B1 (claim 20), and Group C1 (claims 23 and 53) is acknowledged.

2. Claims 13 – 16, 21, 24, 26 – 51, 52 and 54 are acknowledged as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species.

Status of the Claims

3. Currently, claims 1 – 12, 17 – 20, 22, 23, 25 and 53 are pending and under examination.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

On page 6, lines 1-4, the reference characters "grooves or ridges 42" and "threshold 44" are disclosed with respect to Figure 4a, however, these reference numbers are not displayed in Figure 4a.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Figure 5a displays the reference numbers "52" and "58," which are not disclosed in the specification with respect to Figure 5a.

Figure 5b also displays reference number "58," which is not disclosed in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2 and 6 – 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase "said second projections adapted to prevent said component to be separated from liquid sample from substantially leaving said receiving zone," which is vague and indefinite because it is unclear if said "second projections" prevent said component from leaving said receiving zone, or if said "second projections" prevent said component from being separated from the liquid sample.

Claims 6 - 8, which are all ultimately dependent on claim 1, recite the term "said second projections," which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 6, 9, 23 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Buechler (US 6,767,510).

Buechler teaches a device for the separation of a component in a liquid sample prior to the detection of an analyte in said liquid sample, said device having a non-porous substrate 9 comprising:

a sample addition (receiving) zone 1;

a substrate surface;

a filter element or sample reaction barrier 3 (separator element) wherein said filter element or sample reaction barrier is provided adjacent to or in said sample addition zone; and

a diagnostic element 6 (transport or incubation zone) connected to said sample addition zone, thereby forming a flow path on said substrate, wherein at least a part of said flow path consists of areas of projections or grooves substantially vertical to said substrate surface, said projections or grooves having a height, a diameter, and a reciprocal spacing such that lateral capillary flow of said liquid sample in said diagnostic element may be achieved (see Figures 1, 1A, 5, 9B, 6C, and 15; column 3, lines 36-67; column 4, lines 1-67; column 5, lines 1-13; column 7, lines 45-60; column 8, lines 38-66; column 9, lines 2-67; column 10, lines 1-37; column 15, lines 61-65; column 16, lines 59-64; column 18, lines 6-26; and column 27, lines 48-52).

With respect to Applicant's claim 2, the "separator element" can comprise either the filter element or the sample reaction barrier 3. However, when the "separator element" encompasses the sample reaction barrier 3, the barrier consists of an area on said substrate having second

projections or grooves substantially vertical to the surface of said substrate, and having a height, diameter, and reciprocal spacing, where said projections or grooves are capable of substantially preventing a component from substantially leaving said sample addition zone (see Figures 1 and 1A; column 9, lines 27-67; column 10, lines 1-8; and column 27, lines 27-47).

With respect to Applicant's claim 6, the second projections or grooves have a reciprocal spacing in the interval of 0.02 – 0.1 mm (i.e. 20 to 100 microns) (see column 9, lines 27-51).

With respect to Applicant's claim 9, said sample addition zone forms a reaction chamber 4 (basin) adapted to contain a part of the sample separation by said filter element or sample reaction barrier 3 (see Figure 1; column7, lines 50-56; and column 10, lines 31-37).

With respect to Applicant's claims 23 and 53, the substrate is plastic, such as a thermoplastic material (see column 6, lines 23-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3 – 5 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (US 6,767,510) in view of Doshi et al. (US 5,660,798).

The Buechler reference, which was discussed in the 102(e) rejection above, fails to teach that said sample addition zone further contains an enhancing element adapted to enhance the separation capability of said filter or sample reaction barrier (separator element), wherein said enhancing element are compounds capable of forming aggregates of said component to be separated.

Doshi et al. teach an apparatus for red blood cell separation, wherein the apparatus comprises at least one porous material that contains an agglutinating agent. The agglutinating agent is provided in order to rapidly agglutinate red blood cells contained within a test sample applied to the apparatus, wherein the agglutinating of the blood cells allows for the substantially complete removal of the red blood cells from the sample in order to conduct a downstream analyte assay of the sample, which is free from red blood cells capable of interfering with the assay results (see Abstract; Figure 3; column 5, lines 13-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter and/or sample reaction barrier of Buechler an enhancing or agglutinating agent as taught by Doshi et al. because Doshi et al. teach the benefit of providing an agglutinating agent with a device used for applying a test sample and running an analyte assay because the agglutinating agent rapidly agglutinates red blood cells contained within an applied test sample, which allows for the substantially complete removal of the red

blood cells from the sample in order to conduct a downstream assay of the sample, which is free from red blood cells capable of interfering with the assay results.

With respect to Applicant's claims 5 and 25, the time gate 5 taught by Buecher could also read on the separation element of the instant application, wherein the time gate can comprise latex particles that are provided adjacent to the sample addition zone (see Figures 1 and 1A; column 11, lines 34-57; and column 12, lines 22-28). Therefore, it would have been obvious to include with these latex particles taught by Buechler an agglutinating agent as taught by Doshi et al. for the same reasons discussed directly above.

9. Claims 7, 8, 10 – 12, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (US 6,767,510) in view of Ohman et al. (WO 03/103835).

Buechler further fails to teach that the reciprocal spacing of the second projections varies; or that said separator element has a specific affinity, such as a compound that is soluble or dispersible in said liquid sample, for said component to be separated.

Ohman et al. teach microfluidic systems, which comprise a substrate including a flow path that comprises a plurality of microposts (i.e. projections) being small enough to induce capillary action of a liquid sample applied to said flow path. The spacing between said plurality of microposts is further selected so as to induce capillary action in a liquid sample applied anywhere to said flow path, so as to force said liquid to move from where said liquid sample was applied. In addition, the spacing between said microposts can be used to form a gradient, wherein the gradient can function to delay the passage of certain biological and/or chemical entities. Further, the application of reactive substances, which have affinity for various

biological and non-biological substances, to the surfaces of the substrate is provided in order to allow for the binding and removal of substances contained within the test sample that one wishes to separate from the sample (see Abstract; Figure 12; p4, lines 24-30; p5, line 1; p9, lines 19-25; p12, lines 16-24; and p13, lines 18-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the spacing of the grooves in the device of Buechler as taught by Ohman et al. because Ohman et al. teach the benefit of determining optimal spacing between projections provided on a device used in the application of a test sample in order to induce capillary action in a liquid sample applied anywhere to said device, wherein the spacing between said projections can further be used to form a gradient, wherein the gradient can function to delay the passage of certain biological and/or chemical entities. In addition, it would have been obvious to provide a reactive substance (i.e. compound) with the filter and/or sample reaction barrier of Buechler as taught by Ohman et al. because Ohman et al. teach the benefit of applying reactive substances, which have affinity for various biological and non-biological substances, to the surfaces of the substrate (i.e. projections or grooves) in order to allow for the binding and removal of substances contained within the test sample that one wishes to separate from the sample.

With respect to Applicant's claim 17, Buechler teaches that said sample addition zone forms a reaction chamber 4 (basin) adapted to contain a part of the sample separation by said filter element or sample reaction barrier 3 (see Figure 1; column7, lines 50-56; and column 10, lines 31-37).

With respect to Applicant's claim 18, Ohman et al. teach the inclusion of magnet in or around the flow path provided on the substrate in order to provide for the detection of magnetic

substances, wherein coated magnetic particles can be included with the device in order to bind to and separate target assay substances for detection (see p13, lines 2-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include with the device of Buechler a magnet as taught by Ohman et al. in order to provide for the detection of magnetic substances, wherein coated magnetic particles can further be included with the device of Buechler in order to bind to and separate target assay substances for detection.

10. Claims 19, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (US 6,767,510) in view of Diamond (US 2002/0142351).

Buechler further fails to teach the separation element comprises an element for subjecting the sample to ultrasonic standing waves, wherein the device includes at least two ultrasonic energy sources.

Diamond teaches a peptide or protein microassay method and apparatus, wherein the apparatus comprises a substrate with a plurality of deposited microarray dots comprising peptides or proteins of interest. Preferably, the sample applied to the substrate is an aerosolized sample, wherein an aerosolized sample can be generated by applying ultrasonic waves to the test sample. The aerosolized sample generated by the ultrasonic energy has droplet sizes ranging from 1 to 25 micrometers, wherein the aerosolizing of the sample provides for focused sample application, which allows for the sample to be absorbed by the individual microarray dots while any excess sample droplets between the dots tend to either migrate toward the nearest dot to be absorbed or evaporate, thus preventing contamination (see Abstract; and paragraphs [0011], [0035], and [0054]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Buechler a means for providing ultrasonic energy as taught by Diamond because Diamond teaches the benefit of providing a means to supply ultrasonic energy to a device and a sample that is applied to the device in order to acrosolize the sample through the ultrasonic energy, which creates microdroplets of the sample allowing for focused sample application to a device substrate, which ultimately prevents contamination.

With respect to Applicant's claim 22, Buechler teaches that said sample addition zone forms a reaction chamber 4 (basin) adapted to contain a part of the sample separation by said filter element or sample reaction barrier 3 (see Figure 1; column7, lines 50-56; and column 10, lines 31-37).

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
April 22, 2009